Background Document from Technical Work Group

November 30, 2005

During the course of discussions of the Technical Work Group (TWG) and subgroups, questions were raised that could impact the work of the TWG, but that the group considered to be fundamental policy issues. These policy issues could potentially impact how pilot studies are designed, how reporting limits (L_Q, L_D, or L_C) are set, and how compliance is evaluated. The TWG requested this document be sent to the federal advisory committee as background information. The TWG is providing commentary on the following issues:

A) Issue 1: Descriptive vs. Prescriptive

There are two fundamentally different approaches to how reporting limits are set and used. The two approaches are described as "Prescriptive" and "Descriptive." Depending on which approach is used, the work of the TWG is fundamentally shifted.

One proposed method is to examine both approaches in parallel and present the results as such. However this would be a very large time and cost intensive approach. If the FACDQ were to decide on only one of these approaches, the TWG would be able to focus its work more effectively.

1) The Descriptive Approach – an approach where laboratory data is used to describe that lab's L_Q, L_D, and L_C for that lab. It is then up to a client or agency to determine whether these values are acceptable.

    a. Each laboratory determines their own specific L_Q, L_D, and/or L_C by means of a statistical procedure set in regulation for each analyte and analytical method.

    b. These descriptive estimates of L_Q, L_D, and L_C change over time for a specific laboratory. The determination of the L_Q, L_D, and/or L_C may be periodic (e.g. once per year) or on-going (like a running average).

    c. If any of these estimate were selected to act as the Compliance Evaluation Threshold (CET), the CET would change depending on which laboratory is analyzing the samples and the CET are reassessed over time at a particular laboratory and vary between laboratories.

    d. This is how the MDL is currently being used in CWA monitoring.

    e. Using a descriptive approach would favor conducting a single-laboratory pilot study design. Because it is up to a single laboratory to describe its own L_Q, L_D, and L_C and demonstrate these meet reporting limits.

2) The Prescriptive Approach -- an approach where L_Q, L_D, and / or L_C is set in regulation and is the same for a given regulated analyte for all laboratories. It is important to note, the laboratory may not be required to perform a formal L_Q, L_D, L_C study for this approach; simply validating their procedures and equipment meet the requirements being prescribed.

    a. These values would not change over time or between laboratories.

    b. If L_Q, L_D, and/or L_C are used as a CET, the CET is the same for all permit holders irrespective which laboratory or instrumentation they use or changes over time.

    c. This is the approach used in the Information Collection Rule and the Unregulated Chemical Monitoring Rule and the California Drinking Water primacy program.

    d. As outlined in B) Issue 2, the laboratory would on an ongoing basis analyze a validation sample to demonstrate compliance. That sample will require a range of limits.

    e. Using a prescriptive approach would probably favor a multi-laboratory pilot study design as a regulator would require data from many laboratories to sufficiently define and prescribe reporting limits for the laboratories under its jurisdiction.

3) Combined Approach – It is possible to combine both approaches. For example, The California CWA primacy program has a mixture of these two approaches. The L_Q is set prescriptively and the L_C is set descriptively. Other permutations are also possible.

B) Issue 2: Verification of L_Q, L_D, and L_C.

A second policy question that impacts the work of the TWG is: Do L_Q, L_D, and L_C need to be verified? If a laboratory describes estimates of L_Q, L_D and/or L_C or if the laboratory has a prescribed L_Q, L_C, or L_D; should there be procedures in place to verify that the laboratory can actually measure analytes at those levels in the way expected. If verification is required then the TWG can recommend how to do this. There are two alternatives:

1) The individual laboratory does **not** verify the L_C, L_D, or L_Q it is using (whether descriptive or prescriptive) actually meets the definitions used (e.g. a false positive rate of 1% for unspiked blanks and a 50% false negative rate for spiked blanks at L_C). As with the current Appendix B descriptive approach, the laboratory runs and keeps on file a copy of the MDL studies it performed at a snapshot in time. There is no requirement in Appendix B to verify this value.

2) Each individual laboratory verifies L_Q, L_D, and/or L_C by some standardized procedure with performance characteristics. This may be periodic or batch specific.

    a. Using a descriptive approach, a laboratory may do a L_C or L_D determination (e.g. an MDL study). Then the laboratory would have run a series of unspiked and spiked blanks to determine the false positive and false negative rates and see if they match the expected rates.

    b. Using a descriptive approach, a commonly used technique is to analyze check solutions with a concentration at or below the L_Q which must be recovered within certain accuracy limits. Blanks must not have higher concentrations than L_D or L_C. L_C or L_D must be no more than a fixed fraction of L_Q. Laboratories must pass on a batch by batch basis these QC requirements or the data may not be submitted.

    c. Verification for a descriptive approach is generally very complex and costly while verification under a prescriptive approach is a great deal simpler and less expensive.

    d. Using a prescriptive approach, the laboratory simply analyzes a validation sample at or below the L_Q, which must meet recovery requirements set out by method or procedure.

    e. Verification procedures have more commonly used historically with the prescriptive rather than descriptive approach.

C) Issue 3: Lowest possible L_Q, L_D, or L_C

Do L_Q, L_D, and L_C need to be the “absolute lowest possible” for all analytes in all situations?

1) Determining the lowest possible L_Q, L_D, or L_C requires a great deal more effort and cost. This is true irrespective of whether this lowest possible value is set descriptively or prescriptively.

2) Verification of L_Q, L_D, and L_C is much more complicated the lower the concentration is. Also the verification techniques will be different depending on whether one is seeking the lowest possible value in every case.

3) The lowest possible L_Q, L_D, and L_C would probably favor using a descriptive approach and a single-laboratory study design.

4) Study design would be much simpler if L_D and/or L_C were only needed for analytes with very low WQBELs.